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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,782	08/17/2006	Toru Koyanagi	294484US0PCT	9858
22850	7590	10/10/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
MORRIS, PATRICIA L				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
10/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/589,782

Applicant(s)

KOYANAGI ET AL.

Examiner

Patricia L. Morris

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
- Paper No(s)/Mail Date 8/17/06/12/26/06
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1–21 are under consideration in this application.

Election/Restrictions

Applicant's election with traverse of Group I and process (2) of claim 14 in the reply filed on July 7, 2008 is acknowledged. The traversal is on the ground(s) that claims 15-20 are compositions claims. Claims 15-20 were restricted out because they are **not proper composition claims**. Applicants were given the opportunity to amend the claims to put them in proper form but they have failed to do so. Claims 15-20 violate 35 U.S.C. 101 and 112. However, in order to expedite prosecution, claims 15-20 will be treated as compositions based on applicants' assertions that they are indeed compositions claims.

Clearly 37 CFR 1.475 means one when they say a. See the commentary on the rules, 1134 OG 194-209. Note specifically, p. 1134 O.G. 197, col. 2 paragraph numbered (6). PCT Rule 13 provides "claims are permitted to one product, one process of manufacturing the product, and one use of the product". If multiple products, process of manufacture or uses are claimed, the first invention in the category first mentioned in the claims would be considered as the elected invention". Claim 14 will be examined to the extent readable on process 2.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

The requirement is still deemed sound and proper and is therefore maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Lahm et al. I (WO 03/015518), II (WO 03/015519), Berger et al. (US 2004/0209923) in view of Hughes et al. (US 7,247,647).

Lahm et al. I, II and Berger et al. teach closely related compounds for the same use that differ only in having A represent alkyl rather than applicants' alkyl substituted by cycloalkyl. Note, for example, the compounds of formula (I) of Lahm et al. I, II wherein R³ represents alkyl. However, Hughes et al. teach that the alkyl may be substituted by cycloalkyl in the same position on analogous compounds. Note the definition of R⁴ therein.

One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus. The motivation to

make these compounds is their close structural similarities to the disclosed compound. Note that the disclosed compounds have pesticidal activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties. While homology is considered to be present even if true “homology” is not present, such does not defeat the prima facie case of obviousness raised by the art. Attention, in this regard is directed to *In re Druey et al.*, 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court’s opinion, stated:

that “We need not decide here whether the compounds in question are properly labeled in homologues. It appears to us from the authorities cited by the solicitor and appellants the term homologue is used by chemists at times in a broad sense, and at other times a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound.” 50 CCPA 1541.

Also, as the Court stated in *In re Payne et al.*, 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

“the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound.”

In addition, any question of why would one conceive and use the similar compounds (i.e. “motivation”) is answered by the Court in *In re Gyurik et al.*, 596 F.2d 1012, 201 USPQ 552 at 557.

“In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the prima facie case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.”

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of *Lahm et al.* I, II, *Berger et al.* and *Hughes et al.*

Lahm et al. I, II, Berger et al. and Hughes et al. disclose the instant process. Note scheme 6 of Lahm et al. I, II, scheme 7 of Berger et al. and scheme 6 of Hughes et al. As here, a benzoxazinone of formula (IV) is reacted with an amine of formula (V). The reaction of a specific benzoxazinone with an amine does not render the process step itself patentable, anew; In re Albertson, 141 USPQ 730, which was specifically reaffirmed on the last page of In re Kuchl, 177 USPQ 250. Berger et al. in section [0068] states that the general reaction of benzoxazinones with amines to produce anthranilamides is well documented in the chemical literature.

One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product, because he would have expected the analogous starting materials to react similarly. It has been held that application of an old process to a new and analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of insects and worms, does not reasonably provide enablement for the treatment and prevention of all invertebrate pests. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

No enablement is shown for the treatment of pests such as bacteria, fungi, bacteria, etc.

Claims 1-3 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression which may be substituted is employed with considerable abandon in claims 1-3 and 14 with no indication given as to what the groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouché, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention

The nature of the invention is the preparation of a compound and its salts.

State of the Prior Art

Substituents can have very different properties. Substituents tend to convert from less stable to more stable forms. No method exists to predict what substituent will work with any significant certainty. Substituents can convert from one form to another during the manufacturing process will change the pesticidal affects of the drug. This is why it is important to monitor the compounds during manufacture of the drug to see if it persists during manufacture.

The amount of direction or guidance and the presence or absence of working examples

The specification fails to describe any substituent. Substituents often change into other forms during drug manufacture. Based on the unpredictability in the art, applicants are not entitled to any and all unknown substituents.

The breadth of the claims

The breadth of the claims is drawn to the preparation of the compound and its salts.

The quantity of experimentation needed

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the process of preparing all unknown solvates.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by

applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Genentech Inc v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and [p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression which may be substituted in claims 1-3 and 14 is to its meaning.

Claims 15-20 provide for the uses as parasites, pesticides, etc., but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 15-20 are improper composition claims because they fail to recite the present of an inert carrier. Moreover, the term "containing" is open-ended and allows for the inclusion of other active ingredients. The terms pesticide, insecticide, miticide, agent, etc., do not clearly define the claims as compositions. Further, claims 15-20 are substantial duplicates.

The claims measure the invention. *United Carbon Co. V. Binney & Smith Co.*, 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 USPQ 11, at 15.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Patricia L. Morris/
Primary Examiner, Art Unit 1625

plm
September 17, 2008